

Background:

The CIRM Medical and Ethical Standards (MES) [regulations](#), title 17 California Code of Regulations, section 100080, require stem cell lines used in CIRM-funded research to be “acceptably derived.” A human embryonic stem cell (hESC) line is considered acceptably derived if it meets **one** of the following criteria:

- (1) the hESC line has been approved by an authorized authority, or
- (2) a SCRO committee has determine the hESC line to have been created according to acceptable derivation criteria, 100080(a)(2).

The National Institutes of Health (NIH) is an authorized authority, and the lines it approves for NIH-funded research are considered by CIRM to be acceptably derived.

Recent Developments:

NIH has developed a new approach to review and approval of hESC lines and has established a Human Embryonic Stem Cell Registry. Under the new NIH standards, the list of lines approved for NIH-funded research is subject to revision, and hESC lines previously approved by NIH may not be listed on the new NIH registry. NIH may also opt to register a cell line with restrictions, so that NIH approval is limited to specified types of research.

CIRM recognizes that its grantee institutions have initiated on-going CIRM-funded research involving hESC lines that were previously approved by NIH, and that institutions may have questions about how the changes at NIH could affect use of those lines in CIRM-funded research. This guidance is intended to assist CIRM-funded researchers and Stem Cell Research Oversight (SCRO) committees applying CIRM regulations.

- If a SCRO committee determines a hESC line to be created according to acceptable derivation criteria under section 100080(a)(2) that determination is not affected by NIH action regarding that line (regardless of whether the line appears on the NIH-registry).
- If a CIRM-funded research project involves an hESC line that was determined to be acceptably derived on the basis of NIH approval of that line, and this determination was made on or before March 9, 2009, research on that line may continue for the remainder of the research project, without regard to subsequent NIH action regarding that cell line.
- After March 9, 2009, a grantee institution may rely on NIH approval (criteria 1) of a hESC line to determine that the cell line is acceptably derived, and that determination must reflect NIH decisions or restrictions in place when the determination is made. A SCRO committee may also properly determine that a hESC line has been acceptably derived (criteria 2), and that determination is not affected by NIH action regarding that line.